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FILING DATE: ***November 03, 2003***

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)

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☐ *Additional inventors are being named on the ___separately numbered sheets attached hereto.*

TITLE OF THE INVENTION (280 characters max)

BALLOON WITH BIFURCATION

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ENCLOSED APPLICATION PARTS (*check all that apply*)

[X] Specification (includes drawings) *Number of Pages* 6 ☐ CD(s), Number

[X] Drawing(s) *Number of sheets* 3 ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

[X] Applicant claims small entity status. See 37 CFR 1.27.

[X] A check or money order is enclosed to cover the filing fees

[X] The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 01-0035

☐ Payment by credit card. Form PTO-2038 is attached.

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

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Date November 3, 2003

REGISTRATION NO. (*if appropriate*) 24,156

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Assistant Commissioner for Patents Alexandria, VA 22313-1450.

BALLOON WITH BIFURCATION

FIELD OF THE INVENTION

The present invention relates generally to vascular catheterization, and specifically to intravascular balloons and stents.

BACKGROUND OF THE INVENTION

Intravascular stents are used for various purposes, including opening occluded blood vessels. Typically, the stent is supplied in a narrow, contracted form, with a deflated balloon contained inside the stent. The stent and balloon are held at the distal end of a catheter. The physician inserts a guide wire into the blood vessel, and then slides the catheter over the wire to position the stent in the proper location. The balloon is then inflated, via a channel in the catheter, causing the stent to expand so as to be anchored in place and hold the vessel open. Once the stent has been expanded, the balloon is deflated and is withdrawn, along with the catheter, from the vessel.

It is sometimes necessary to insert a stent at the location of a bifurcation in an blood vessel. In this case, the stent must be inserted into the main vessel (i.e., the vessel that is to be expanded by the stent) in such a way that the side vessel, which branches from the main vessel at the bifurcation, is not blocked by the stent. For this purpose, the stent typically has an opening in its side, which must be positioned precisely at the bifurcation before the stent is expanded. Bifurcated stents are also known in the art, but they are complicated to use and have not gained wide acceptance.

SUMMARY OF THE INVENTION

Embodiments of the present invention provide a novel bifurcated balloon and methods for using the balloon in intravascular procedures performed at vascular bifurcations. The balloon comprises a main, longitudinal section, with a radial protrusion at a predefined location along the length of the main section.

The balloon is typically used inside a stent having a side opening, such that when inflated, the radial protrusion of the balloon protrudes through the side opening of the stent. The physician partially inflates the balloon, and then uses the protrusion to align the side opening of the stent with the side vessel at the bifurcation. Once the stent has been properly aligned in this manner, the balloon is fully inflated, causing the stent to expand and thus to be anchored in place, in optimal alignment with the side vessel. The balloon is then deflated and withdrawn.

Alternatively, the balloon may be used independently of a stent, for example, in balloon catheterization procedures to open occluded blood vessels near bifurcations in the vessels. In this case, the radial protrusion of the balloon into the side vessel is still useful in preventing plaques at or near the bifurcation from breaking loose as the main vessel is expanded. This added benefit of preventing plaque release may also be provided when the bifurcated balloon is used in expanding a stent, as described above.

The present invention will be more fully understood from the following detailed description of the embodiments thereof, taken together with the drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1-3 are schematic, pictorial illustrations showing successive stages in insertion of a stent into a blood vessel and alignment of the stent with a bifurcation in the blood vessel, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Fig. 1 schematically illustrates insertion of a stent 20 over a guide wire 21 in a blood vessel 22 to the location of a bifurcation in the vessel. The stent is inserted in a contracted state, with a deflated balloon (not seen in this figure) inside the stent. The stent is positioned in the main vessel 22, and has a side opening 26 that must be aligned with a side vessel 24 at the bifurcation, to permit blood flow in the side vessel after the stent has been expanded. The main and side vessels are partially occluded by plaques 28.

In the next stage, shown in Fig. 2, the balloon inside the stent is partially inflated, causing a radial protrusion 30 of the balloon to protrude through the side opening of the stent. Typically, for this purpose, the balloon is inflated to a low pressure, for example, about ¼ atm, via a fluid channel in the catheter (not shown) that is used to insert the stent. The low pressure is sufficient to cause the radial protrusion to expand through the side opening, but is not sufficient to cause the main body of the balloon (inside the stent) to make the stent itself expand.

The operating physician performs two steps in order to align the side opening of the stent with the side vessel: rotation of the stent about its longitudinal

axis, and longitudinal motion of the stent along the axis. Typically, the physician uses X-ray imaging or other radiographic imaging of the blood vessels and stent for assistance during these steps. Additionally or alternatively, protrusion 30 of the balloon may give the physician tactile feedback, indicating when the protrusion has entered the opening of the side vessel. In some embodiments, the balloon is partially inflated, as shown in Fig. 2, prior to the rotation step. In other embodiments, the balloon is partially inflated only after the stent has been turned to the proper orientation, and the protrusion of the balloon is thus used primarily for longitudinal alignment of the side opening of the stent with the side vessel.

In some embodiments, the balloon is inflated with a radiopaque fluid, such as saline solution mixed with a suitable contrast agent. The operating physician is then able to see the balloon - and in particular to see the location of the radial protrusion of the balloon - under X-ray imaging. Until the side opening of the stent is properly positioned adjacent to the entrance of the side vessel at the bifurcation, the radial protrusion of the balloon will be at least partly compressed by the walls of the main vessel or by plaques within the vessel. When the side opening of the stent is properly aligned, however, the physician will see that the radial protrusion of the balloon has expanded outward into the side vessel, as shown in Fig. 2.

After the stent has been correctly positioned using the partially-inflated balloon, the balloon is inflated to full pressure, as shown in Fig. 3. For example, the pressure in the balloon may be increased at this point to

about 1.5 to 2 atm, which is typically sufficient to expand the stent. In the embodiment shown in Fig. 3, the radial protrusion of the stent expands further under the increased pressure, and presses against the plaques in the area of the bifurcation. Expansion of the balloon protrusion has two desirable effects: (1) During expansion of the stent, the protrusion holds the side opening of the stent in precise alignment with the side vessel. (2) The balloon helps to prevent the plaques from breaking loose from the vessel walls while the stent is being expanded. When such plaques do break loose, they can cause dangerous and even fatal results downstream. This latter anti-embolic effect of the bifurcated balloon is also useful when the balloon alone is used to expand a bifurcated vessel, even in the absence of a stent.

Once the stent has been fully expanded, the balloon is once again deflated and is then withdrawn from the vessel, leaving the stent in place. (The guide wire is also withdrawn, of course.) The radial protrusion of the balloon is made small enough so that upon deflation, it is drawn back through the side opening of the stent, without risk of being stuck in place. The protrusion may be made of a flexible but relatively inelastic material, to prevent it from being overinflated when high pressure is applied to expand the stent.

Although the figures here illustrate a certain configuration of the vessel bifurcation, stent and balloon, this configuration is shown only by way of example. Alternative configurations based on the principles of the present invention will be apparent to those skilled in the art. For example, although the

vessel bifurcation (and consequently the balloon shown here) has a "T" shape, in other embodiments of the present invention, the balloon may be "Y" shaped, or may have other, more complex shapes, according to the configuration of the blood vessels in which the balloon is to be used. Whereas the balloon shown in the figures is configured for insertion over a guide wire, the balloon (and the catheter used to insert it) may alternatively be configured for operation without a guide wire, or for insertion using two or more guide wires if appropriate. The radial protrusion of the balloon may also be separated from the main portion of the balloon, and may thus be inflated via a different channel, and to a different pressure, if desired, from the main portion of the balloon.

It will thus be appreciated that the embodiments described above are cited by way of example, and that the present invention is not limited to what has been particularly shown and described hereinabove. Rather, the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove, as well as variations and modifications thereof which would occur to persons skilled in the art upon reading the foregoing description and which are not disclosed in the prior art.

FIGURES

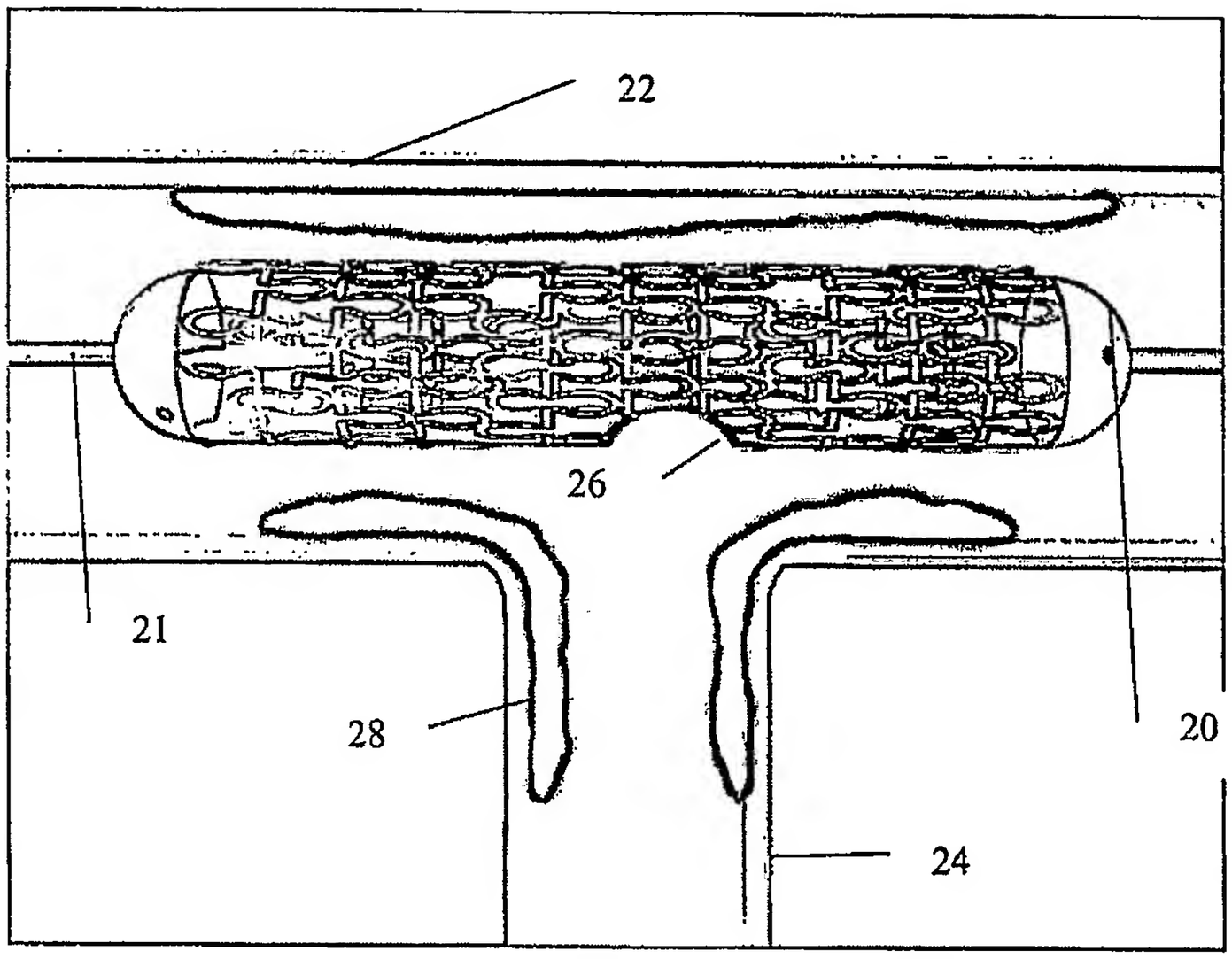

Fig. 1

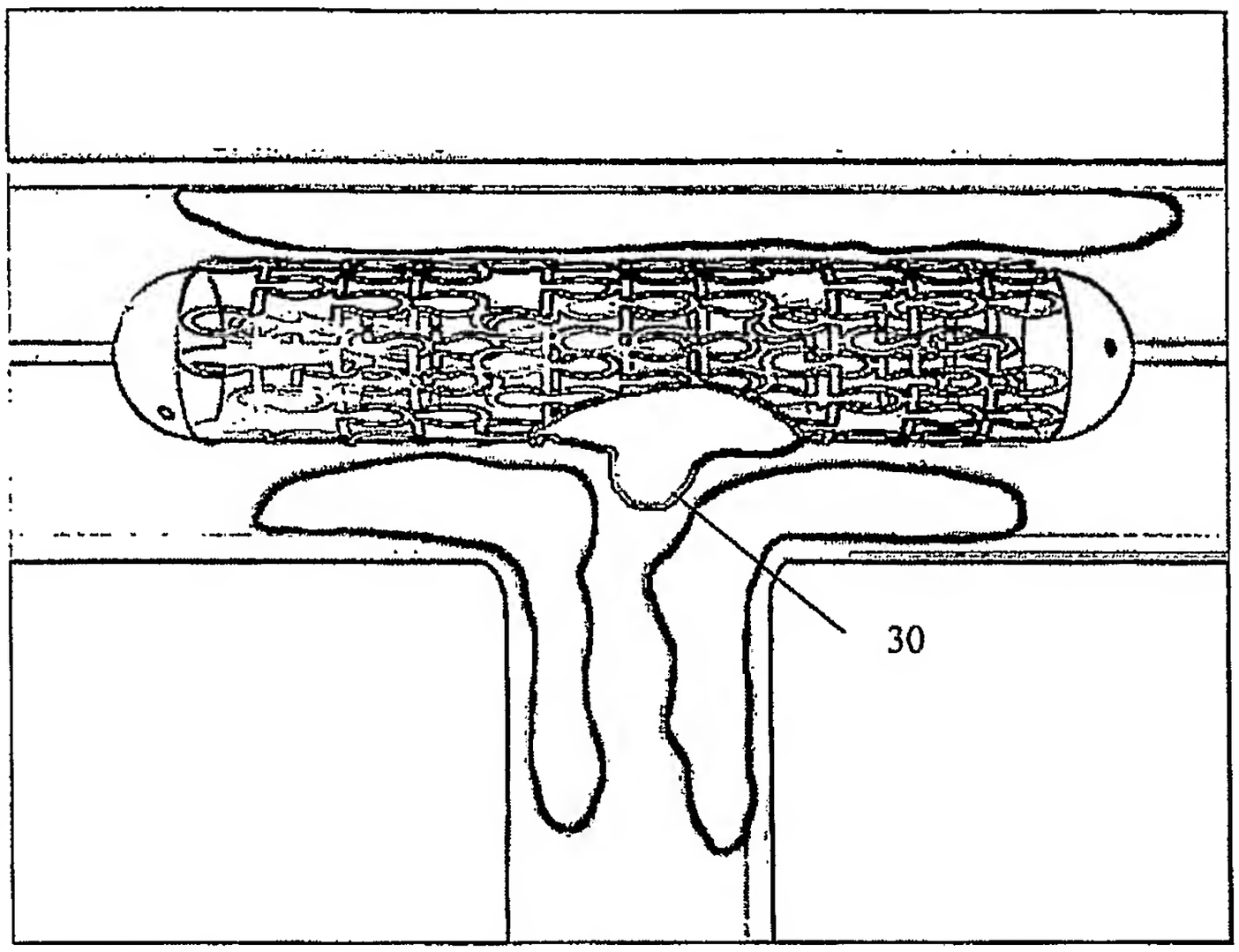

Fig. 2

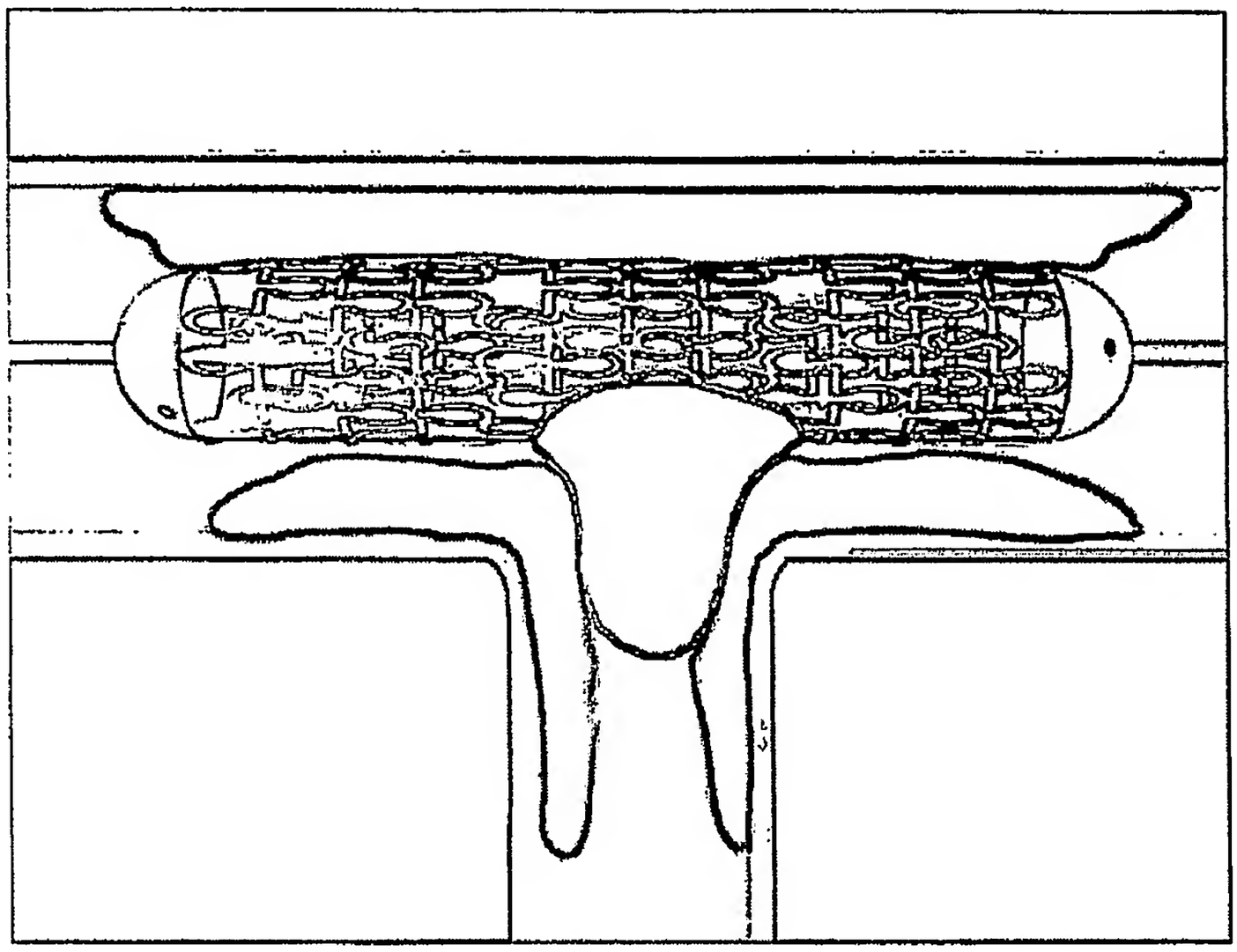

Fig. 3